DEPARTMENT OF HEALTH AND HUMAN SERVICES

950784

Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
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November 12, 2004

Warning Letter No. 2005-NOL-03

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Murray L. Beard, CEO
Clarity, Inc.
8500 Wolf Lake Drive, Suite 110
Memphis, Tennessee 38184

Dear Mr. Beard:

On August 19-25, 2004, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your facility, Grace Medical, Inc., 7731 US Highway 70, Suite 107, Bartlett, Tennessee 38133-2095. This inspection determined your firm manufactures otologic implant products. These products are medical devices under the Federal Food, Drug, and Cosmetic Act (the Act), because they are intended for use in diagnosing or treating a medical condition or to affect the structure or a function of the body (section 201(h) of the Act). You can find the Act and the CFR through links in FDA's home page at http://www.fda.gov.

The above-stated inspection revealed the devices to be adulterated within the meaning of section 501(h) of the Act [21 USC 351(h)] in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation, as specified in Title 21 of the *Code of Federal Regulations* (CFR), Part 820. Specific Quality System violations include:

1. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures, as required by 21 CFR 820.20(c). Specifically, management review meetings have not been conducted annually in accordance with your firm's internal procedures.

2. Failure to conduct quality audits in accordance with your firm's internal procedures to assure the Quality System is in compliance with the established system requirements, as required by 21 CFR 820.22.

3. Failure to have complete procedures to control the design process of the device, as required by 21 CFR 820.30(a). Specifically, Design Control Procedure #COP 73001 fails to describe the interfaces with different groups or activities that provide input to the design and development process. Additionally, the procedure fails to ensure that an individual who does not have direct responsibility for the design stage being reviewed participates in the design review meeting.

4. Failure to control production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). Specifically, Routine [redacted] Run #141 dated 5/21/04, #145 dated 6/22/04, and #144 dated 7/12/04, had pressures above the validated process specifications.

5. Failure to validate processes with a high degree of assurance where the results of the processes cannot be fully verified by subsequent inspections and tests, as required by 21 CFR 820.75(a). Specifically:

   - The hydrogen peroxide sterilization validation study conducted on the [redacted] Sterilizer failed to include evaluation of upper and lower parameters; and biological indicators were not placed in worst case scenario positions.

   - There is no validation study of the shipping process to determine that devices inside the shipping containers are not adversely affected by the shipping process.

   - The validation study for the [redacted] did not include more than one run, which was conducted without product.

6. Failure to document software validation activities for computers or automated data processing systems used as part of production, as required by 21 CFR 820.70(i). Specifically, there is no documentation indicating the automated [redacted] lathes and mills, used to manufacture device implants, have been validated.

7. Failure to verify and validate changes to specifications, specifically for DCF #370, 394, 408, and 409, and failure to have written procedures describing the steps to take and actions required in implementing changes to production methods and processes, as required by 21 CFR 820.70(b).

8. Failure to document acceptance activities to verify the products meet specifications for the Flouroplastic Stape Protheses and Piston devices, as required by 21 CFR 820.80(e).

9. Failure to establish and maintain complete procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100. Specifically:

   - Corrective and preventive action procedure GMI #85201 does not explain the activities and methods to be used in analyzing quality sources. Additionally, it fails to describe activities or identify actions to be taken in correcting and preventing the recurrence of nonconforming product. [21 CFR 820.100(b)]

   - There is no documentation that customer complaints and nonconforming reports have been analyzed/trended in accordance with corrective and preventive action procedure GMI #85201. Additionally, the procedure does not include acceptance activities as a source of quality data to be analyzed/trended to identify existing and potential causes of nonconforming product. [21 CFR 820.100(a)(1)]

- Corrective and preventive action procedure GMI #85201 and complaint procedure GMI #83002 do not describe or identify the actions to be taken or methods to be used in conducting failure investigations of in house nonconformities and confirmed device failures resulting from consumer complaints. [21 CFR 820.100(a)(2)]

10. Failure to document investigation activities for complaint numbers 71, 65, and 57 concerning confirmed device failures, as required by 21 CFR 820.198 (c) and (e).

FDA has reviewed your October 1, 2004 response to the Form FDA 483 issued after the most recent inspection. This response was inadequate.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, which may include the refused entry of your affected products until the corrections are completed.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure similar violations will not recur.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to the attention of Kimberly L. McMillan, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217. If you have any questions concerning the violations noted, please contact Ms. McMillan at (615) 781-5380 extension 138.

Sincerely,

Dwight Ward, ADD for

H. Tyler Thornburg
Director, New Orleans District